

PATENT

Attorney's Docket No. 381-72 CIP

Applicant or Patentee: Waksal

Serial or Patent No.: 09/374,028

Filed or Issued: August 13, 1999

For: TREATMENT OF REFRACTORY HUMAN TUMORS WITH EPIDERMAL
GROWTH FACTOR RECEPTOR ANTAGONISTS

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(c))--SMALL BUSINESS CONCERN**

I hereby declare that I am

☐ the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern

identified below:

NAME OF CONCERN ImClone Systems Incorporated

ADDRESS OF CONCERN 180 Varick Street, New York, New York 10014

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed, to and remain with the small business concern identified above with regard to the invention, entitled:

**TREATMENT OF REFRACTORY HUMAN TUMORS WITH EPIDERMAL
GROWTH FACTORS RECEPTOR ANTAGONISTS**

by inventor(s) Harlan Waksal

described in:

- ☐ the specification filed herewith.
☒ application serial no. 09/374,028, filed August 13, 1999.
☐ patent no. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 35 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Harlan Waksal

TITLE OF PERSON OTHER THAN OWNER Chief Operating Officer

ADDRESS OF PERSON SIGNING ImClone Systems Incorporated
180 Varick Street, New York, New York 10014

SIGNATURE _____

Date 11/30/99

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL,
DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one)

- | | |
|---------------------------------------|--|
| <input type="checkbox"/> Original | <input type="checkbox"/> National Stage PCT |
| <input type="checkbox"/> Supplemental | <input type="checkbox"/> Divisional |
| <input type="checkbox"/> Design | <input type="checkbox"/> Continuation |
| | <input checked="" type="checkbox"/> Continuation-in-Part (CIP) |

INVENTORSHIP IDENTIFICATION

NOTE: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TREATMENT OF REFRACTORY HUMAN TUMORS WITH EPIDERMAL
GROWTH FACTOR RECEPTOR ANTAGONISTS

the specification of which: (complete (a), (b) or (c))

- (a) ☐ is attached hereto.
- (b) ☒ was filed on August 13, 1999 as
☒ Serial No. 09/374,028 or
☐ Express Mail No. _____, as Serial No. not yet known
and was amended on _____. (If applicable)
- (c) ☐ was described and claimed in PCT International Application No. PCT/
filed on _____ and as amended under PCT Article 19 on _____. (If any)

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above, and that the filing of said specification, if heretofore filed, was authorized by me.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

CLAIM OF PRIORITY OF EARLIER FOREIGN APPLICATION(S) UNDER 35 U.S.C. §119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

(List prior foreign/PCT application(s) filed within 12 months (6 months for design) prior to this U.S. application.)

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (or PCT)	APPLICATION NO.	DATE OF FILING (Day/Month/Year)	PRIORITY CLAIMED UNDER 35 USC §119
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) UNDER 35 U.S.C. §119(e)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(List prior U.S. provisional applications.)

PROVISIONAL APPLICATION NO.	FILING DATE (Day/Month/Year)

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

(List prior U.S. applications or PCT international applications designating the U.S. for benefit under 35 U.S.C. §120.)

U.S. APPLICATIONS**STATUS** (Check One)

U.S. SERIAL NO.	U.S. FILING DATE (Day/Month/Year)	Patented	Pending	Abandoned
09/312,284	May 14, 1999	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
0 /		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PCT APPLICATIONS DESIGNATING THE U.S.**STATUS** (Check One)

PCT APPLN. NO.	PCT FILING DATE (Day/Month/Year)	U.S. SERIAL NOS. ASSIGNED (If any)	Patented	Pending	Abandoned
PCT/			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCT/			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS

PRIORITY APPLICATION NO.	PRIORITY COUNTRY	FILING DATE (Day/Month/Year)	ISSUE DATE (Day/Month/Year)

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office in connection therewith:

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory W. Bachmann, Reg. No. 41,593; Steven T. Zuschlag, Reg. No. 43,309; Susan A. Sipos, Reg. No. 43,128, Kevin E. McDermott, Reg. No. 35,946; Robert C. Morriss, Reg. No. 42,910; Roderick S.W. Turner, Reg. No. 38,639; James F. Harrington, Reg. No. 44,741; Samir R. Patel, Reg. No. 44,998, and Richard LaCava, Reg. No. 41,135, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No. 30,152; Kirk M. Miles, Reg. No. 37,891; Robert F. Chisholm, Reg. No. 39,939; Kellyanne Merkel, Reg. No. 43,800; and Keith R. Lange, Reg. No. 44,201, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054.

PLEASE SEND CORRESPONDENCE TO:

Irving N. Feit, Esq.
HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791

PLEASE DIRECT TELEPHONE CALLS TO:

Irving N. Feit
(516) 822-3550

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full Name of Sole or First Inventor: **Harlan W. Waksal**

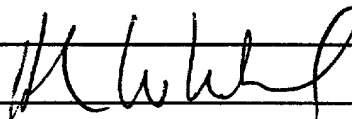
Country of Citizenship: **U.S.A.**

Residence Address: **85 Stonebridge Road, Montclair, New Jersey 07042**

Post Office Address: **Same as Above**

Date: **11/30/99**

Inventor's signature



NOTE: All above spaces identifying inventors must be completed or deleted before any inventor executes this application

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**POWER OF ATTORNEY BY ASSIGNEE OF
ENTIRE INTEREST (REVOCATION OF
PRIOR POWERS AND APPOINTMENT OF
NEW POWER)**

Docket Number: 11245/46602

Application Number: **09/374,028**

Filing Date: **August 13, 1999**

Examiner
J. Nichols

Art Unit
1642

Invention Title: **TREATMENT OF REFRACTORY HUMAN
TUMORS WITH EPIDERMAL GROWTH FACTOR
RECEPTOR ANTAGONISTS**

Inventor(s): **Harlan W. WAKSAL**

Address to:
Assistant Commissioner for Patents
Washington D.C. 20231

As assignee of the entire interest of the above-identified application by virtue of an executed Assignment, filed with the U.S. Patent and Trademark Office on January 28, 2000, (a copy of **Request for Recordation of Assignment Document as filed is attached**), of all powers of attorney previously given are hereby revoked and the following attorneys and/or agents are hereby appointed to prosecute and transact all business in the Patent and Trademark office connected therewith:

Charles R. Brainard (Reg. No. 21,069)
Paul H. Heller (Reg. No. 21,074)
Stuart J. Sinder (Reg. No. 25,377)
Richard L. DeLucia (Reg. No. 28,839)
Richard S. Gresalfi (Reg. No. 31,960)
Steven J. Lee (Reg. No. 31,272)
Estelle J. Tsevdos (Reg. No. 31,145)
Thomas F. Meagher (Reg. No. 29,831)
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Judith L. Toffenetti (Reg. No. 39,048)

Robin A. Chadwick (Reg. No. 36,477)
Pamela G. Salkeld (Reg. No. 38,607)
Charles A. Weiss (Reg. No. 40,867)
M. Lisa Wilson (Reg. No. 34,045)
Kristina M. Jahns (Reg. No. 41,092)
Ronald J. Campbell (Reg. No. 33,842)
Mitul Desai (Reg. No. P-46,661)
Stephan C. Grant (Reg. No. 44,132)
Houri Khalilian (Reg. No. 39,546)
Lawrence P. Casson (Reg. No. P-46,606)
Christopher E. Loh (Reg. No. 46,000)
Neil M. McCarthy (Reg. No. 43-435)

SEND CORRESPONDENCE, AND DIRECT TELEPHONE CALLS TO:

Deborah A. Somerville
KENYON & KENYON
One Broadway
New York, New York 10004
(212) 425-7200 (phone)
(212) 425-5288 (facsimile)

IMCLONE SYSTEMS, INC.

Date: 8/2/00

By: 

Name:

Title: Ronald Martell

Vice-president, marketing

100-5144860

For use in filing and recording only

Docket No. 381-72 CIP

Serial No. 09/374,028

Filed: August 13, 1999

ASSIGNMENT

WHEREAS, I/WE, Harlan W. Waksal, a citizen of The United States of America, residing at 85 Stonebridge Road, Montclair, New Jersey 07042; have made a certain invention in "Treatment of Refractory Human Tumors with Epidermal Growth Factor Receptor Antagonists," said invention being disclosed, shown and described in an application for Letters Patent of the United States filed August 13, 1999, and further identified by Docket Number 381-72 CIP; and

WHEREAS, ImClone Systems Incorporated, 180 Varick Street, New York, New York 10014, a corporation of Delaware, hereinafter called Company), is desirous of acquiring the entire right, title and interest in and to said invention and all Letters Patent that may be granted thereon;

NOW, THEREFORE, in consideration of the premises and in acknowledgement, confirmation and performance of obligations which arose out of the terms and conditions of our employment by, or relationship with, Company or an Affiliate of Company, at the time the invention was made, I/we do hereby sell, transfer and assign to Company, its successors and assigns, the entire right, title and interest in and to said invention, in all countries of the world, and in and to all applications for Letters Patent that may be made therefor, in all countries of the world, including specifically, but not limited to, the aforesaid application and all Letters Patent that may be granted thereon and all divisions, reissues, substitutions, continuations, continuations-in-part and extensions thereof, international applications filed under the Patent Cooperation Treaty, and all rights arising under the International Convention for the Protection of Industrial Property by filing any such applications for Letters Patent. We hereby acknowledge that this assignment, being of the entire right, title and interest in and to said invention, carries with it the right in Company to apply for and obtain from competent authorities in all countries of the world any and all Letters Patent by attorneys and agents of Company's selection and the right to procure the grant of all such Letters Patent to Company in its own name as assignee of the entire right, title and interest therein.

I/we will, at Company's expense, perform all lawful acts that Company, its successors, assigns, nominees and legal representatives may deem advisable to carry out the true purposes and intent hereof and I/we will assist Company, its successors, assigns, nominees and legal representatives, in every lawful way to obtain, sustain and enforce Letters Patent for said invention, in all countries of the world, as and when requested by Company, including specifically, but without limitation, the following:

- (a) I/we will communicate to Company all facts known to us respecting said invention;

- (b) I/we will, as and when requested by Company, execute all lawful papers which Company may deem advisable for carrying out the true purposes and intent hereof, including all lawful oaths and affidavits, one or more written confirmations of this assignment, all applications for Letters Patent in foreign countries and all divisional, continuation, continuation-in-part, reissue and substitute applications for Letters Patent for said invention:
- (c) I/we will testify in any legal proceedings which involve said invention or any Letters Patent granted therefor.

I/we acknowledge and agree that the obligations recited herein are binding on us and on our heirs, executors, administrators and assigns forever.

IN WITNESS WHEREOF, I/we have hereunto set our hands and seals on the dates appearing before our respective names.

DATE 11/7/2000

TYPE Harlan W. Waksal

SIGN 